REMARKS

Claims 1-10 are pending in the Application. Claims 4-10 have been withdrawn from consideration. Claims 1-3 are rejected under 35 U.S.C. § 103(a). Favorable reconsideration and examination of the subject Application in light of the following remarks is respectfully requested.

Specification Amendment

Applicants thank the Examiner for pointing out that an amendment to the specification was needed. The specification is amended in the instant Response to include the reference to the prior-filed applications and provide the relationship between the applications in compliance with 37 C.F.R. § 1.78. *See also* M.P.E.P. § 201.11(V) at 200-64 (8th ed., rev. no. 2).

Claim Rejections under 35 U.S.C. § 103(a)

The Office Action states that claims 1-3 are rejected under 35 U.S.C. §103(a) as unpatentable over Chen et al., WO 96/39176 (the "Chen '176 publication") in view of U.S. Patent No. 4,950,469, issued to Katz (the "Katz '469 patent"). In particular, the Office Action states that

> It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen whilst Katz teaches that [] rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would function as an autoantigen.

(Office Action, p. 4.)

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the U.S. Patent and Trademark Office ("USPTO") has the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. § 2142 at 2100-128 (8th ed., rev. no. 2). Thus, in the absence of such a *prima facie* case, Applicants' claims must be found to be nonobvious. In order for the USPTO to fulfill its burden of

establishing a prima facie case of obviousness, the prior art reference (or references) must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.03 at 2100-133 (8th ed., rev. no. 2).

Applicants respectfully assert that the Chen '176 publication and the Katz '469 patent, whether alone or in combination, do not teach or suggest all of the features present in Applicants' claimed invention.

In particular, neither the Chen '176 publication nor the Katz '469 patent teaches "introducing to said subject a reagent or a combination of reagents . . . comprising a component or components or fragments thereof of said infectious agent" for producing selective immune down regulation. The Chen '176 publication states that its disclosure relates to "methods for orally administering autoantigens" and defines "autoantigen" as "any substance or a portion thereof normally found within a mammal that invokes an immune response within an individual." Chen '176 publication, p. 8, lines 12-14. By contrast, Applicants' claimed invention involves introducing into a subject a substance comprising components or fragments of an infectious bacterial agent for producing selective immune down regulation. Thus, the Chen '176 publication neither teaches nor suggests Applicants' claimed invention. Moreover, the Chen '176 publication relates to high-dose feeding. *See, e.g.*, Chen '176 publication, p. 39, lines 32-35. However, as demonstrated in Example 1 of the specification, the inventors of the instant Application have shown that high does feeding is ineffective. *See* Specification, Example 1; p. 39, para. 1. Unlike high-dose feeding, low-dose feeding inhibited both the humoral and cellular immune responses. *See* Specification, Example 1; p. 39, para. 1.

Such deficiencies in the Chen '176 publication are not remedied by the Katz '469 patent. The Katz '469 patent states that its disclosure relates to "receptor blocking technology" and a "cell-surface receptor binding molecule—D-GL conjugate of the cell surface receptor binding molecule and introducing such D-GL conjugates into the patient." Katz '469 patent, Abstract and col. 2, lines 59-62. The Katz '469 patent, however, does not teach or suggest the feature of Applicants' invention relating to introducing into a subject a substance comprising components or fragments of an infectious bacterial agent for producing selective immune down regulation. In its brief discussion of rheumatic fever, the Katz '469 patent mentions the antigens of cardiac tissue to which "anti-Strep A antibodies" can bind. Katz '469 patent, col. 6, line 16. The Katz '469 patent states that "D-GL conjugates of antigens which specifically bind anti-Strep A antibodies, if injected . . . may be expected to interfere with the autoimmune response which is

believed to be implicated in rheumatic fever . . . As specific autoantigens are identified and isolated, D-GL conjugates thereof may also interfere with the inflammation response and halt or diminish the rate of progress of the disease." Katz '469 patent, col. 6, lines 18-26. Autoantigens are "antigens that are expressed by [the patients'] tissue." Katz '469 patent, col. 6, lines 15-16. Consequently, as the Katz '469 patent discusses injecting D-GL conjugates of autoantigens, the Katz '469 patent does not suggest or teach introducing into a subject a substance comprising components or fragments of an infectious bacterial agent for producing selective immune down regulation.

Accordingly, the invention claimed in the present application would not be *prima facie* obvious, and Applicants respectfully request that the rejection of claims 1-3 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

In view of the above remarks, early notification of a favorable consideration is respectfully requested. If the Examiner believes that the prosecution might be advanced by discussing the Application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Applicants are submitting concurrently with the instant Response a Petition for Three-Month Extension of Time Under 37 C.F.R. § 1.136(a) with a check in the amount of $510.00. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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